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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/755,428 | 01/12/2004 | Roberto Pedros | 2331 CON2 (203-2539CON2) | 9696 |
| Covidien 60 Middletown Avenue North Haven, CT 06473 | | | EXAMINER TYSON, MELANIE RUANO | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/755,428

Applicant(s)

PEDROS ET AL.

Examiner

MELANIE TYSON

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 September 2010 has been entered. Claims 1-17, 19-28, and 35 are cancelled.

Response to Arguments

The amendment made to claim 29 overcomes the previous objection and has been entered.

Applicant's arguments filed 02 September 2010 with respect to claim 18 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 29-34 have been considered, but they are not persuasive. The applicant argues that the attachments of Sutton are not intended to come into contact with tissue during use of the device and even if incidental contact with tissue occurred, the attachments would not "adjoin the tissue adjacent the vascular opening," and are not "configured and dimensioned" to perform this function. However, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the claimed structural limitations. The attachments (40 and 41) clearly have a surface capable of engaging tissue and then

adjoining the tissue adjacent a vascular opening as the device is moved to a closed position. The applicant then argues that the attachments are not positioned in the recesses on the distal end of the shaft, and thus Sutton fails to disclose the attachment members are configured and dimensioned for receipt by the recesses. However, Figure 2 clearly shows the attachments being received by the recesses (either side of 88 formed by 70), in which Sutton further discloses the inner wall 63 being stepped outwardly relative to 70 to provide clearance for the ends of the attachments (see also Figure 4). Therefore, it is the examiner's position that Sutton discloses the attachment members are "configured and dimensioned" for performing all the functions as recited in the claims. The applicant's argument that Fain and Kuehn fail to disclose these deficiencies is moot, since it is the examiner's position that Sutton discloses the limitations argued.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18 and 29-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant the applicant disclosed the contacting surfaces of the

jaw members may act as RF electrodes and may be received in the recesses in the shaft, but failed to disclose at least one of the jaw members includes an attachment member formed of conductive material for facilitating transmission of energy to tissue or dimensioned for receipt by the recesses in the shaft. Therefore, the limitations are considered new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tay et al. (U.S. Patent No. 5,507,744 - cited on 1449 dated 1/12/04) and Kuehn et al. (U.S. Patent No. 6,165,183).

Tay discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (38) having proximal and distal ends and a longitudinal axis (for example, see Figure 1), an elongated shaft (41) at least partially

disposed in the housing, a tissue engaging member (14) disposed adjacent the distal end of the housing (via deployment member 8) and being longitudinally and reciprocally movable relative to the housing to engage tissue (for example, see Figure 15A), two jaw members (50, 50) positioned adjacent the tissue engaging member and being movable independently thereof that close and capable of seizing vascular tissue (for example, see Figure 15), the jaw members each including attachment members formed of conductive material (distal surfaces that engage the tissue), and an energy source connected to the attachment members to facilitate transmission of energy to the tissue to thereby thermally fuse the opening (for example, see column 11, lines 34-67). Tay fails to disclose the tissue engaging member may comprise two hooks or J-shaped configurations disposed in general diametrical opposed relation in the advanced position, wherein the engaging members are composed of a shape memory material such that they are adapted to resume the hook or J-shaped configuration when unstressed.

Kuehn discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (126) and at least two tissue engaging members (470, 472) being adjacent the distal end of the housing (for example, see Figure 22) and being longitudinally, reciprocally, and radially outwardly movable relative to the housing to engage tissue to assist in applying a fastener thereto (for example, see column 10, lines 4-14), each having a distal segment (480, 482) arranged in a general hook or J-shaped configuration being disposed in general diametrical opposed relation and generally curving away from the longitudinal axis when

in an advanced position (for example, see Figure 22), wherein the engaging members have sharpened ends (for example, see column 10, lines 4-14). The substitution of one known element (Kuehn's tissue engaging members) for another (Tay's engaging member) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the tissue engaging members would have yielded predictable results, namely, providing a means for effectively engaging tissue.

Claims 29, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al. (U.S. Patent No. 5,762,613) and Fain et al. (U.S. Patent No. 5,290,299).

Sutton discloses an apparatus (see entire document) capable of substantially closing a vascular opening comprising a housing having proximal and distal ends and a longitudinal axis (for example, see Figure 1), an elongated shaft (14) at least partially positioned within the housing having a lumen configured and dimensioned to receive a guidewire (50) and having recesses formed adjacent the distal end (slot 70 forms a top recess and a bottom recess), and two jaw members (80, 81) that close thus are capable of seizing vascular tissue, wherein the jaw members include attachment members (40, 41) capable of engaging tissue extending from the jaws thus are "configured and dimensioned to adjoin tissue adjacent a vascular opening" as claimed, and wherein the attachment members are configured and dimensioned for receipt by the recesses in the elongated shaft (for example, see Figure 4). Harrison fails to disclose tissue engaging members.

Fain discloses an apparatus (see entire document) capable of substantially closing a vascular opening comprising a housing and jaw members (for example, see Figure 5E). Fain teaches further providing the device with tissue engaging members (44) adjacent the jaw members and the distal end of the housing, wherein the tissue engaging members are longitudinally movable independent of the jaw members. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further provide Sutton's device with tissue engaging members as taught by Fain. Doing so would assist in positioning and holding the selected tissue as the jaw members are utilized, thus enabling the jaw members to be repeatedly opened and closed if so required to effectively accomplish the intended result.

Claims 31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al. and Fain et al. as applied to claim 29 above, and further in view of Kuehn et al. Sutton as modified by Fain fails to disclose the two tissue engaging members comprise two hooks or a J-shaped configuration disposed in general diametrical opposed relation in the advanced position, wherein the engaging members are composed of a shape memory material.

Kuehn discloses an apparatus capable of substantially closing a vascular opening (see entire document) comprising a housing (126) and at least two tissue engaging members (470, 472) being adjacent the distal end of the housing (for example, see Figure 22) and being longitudinally, reciprocally, and radially outwardly movable relative to the housing to engage tissue to assist in applying a fastener thereto (for example, see column 10, lines 4-14), each having a distal segment (480, 482)

arranged in a general hook or J-shaped configuration being disposed in general diametrical opposed relation and generally curving away from the longitudinal axis when in an advanced position (for example, see Figure 22). The substitution of one known element (Kuehn's tissue engaging members) for another (the tissue engaging members of Sutton as modified by Fain) would have been obvious to one of ordinary skill in the art at the time of the invention since the substitution of the tissue engaging members would have yielded predictable results, namely, providing a means for effectively engaging tissue. With further respect to claim 31, shape memory materials are well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the tissue engaging members of a shape memory material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18 and 29-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,248,124.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members [tissue everting members; note that the everting members inherently have a deployment member in order to perform the recited deploying function] that move between jaw members [jaw members disposed about the everting members], wherein the jaw members move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may

not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '124 invention with a spring member to bias the jaw members closed. Doing so would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens or slots for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '124 invention with a guidewire lumen or slot in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Claims 18 and 29-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,676,685 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the

claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members having a deployment member and move between jaw members [jaw members disposed about the everting members], wherein the jaw members move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [thermal transmitting portion or electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be a "thermal transmitting portion" or an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '685 invention with a spring member to bias the jaw members closed. Doing so

would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '685 invention with a guidewire lumen in order to be able to track the device over a properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Claims 18 and 29-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,252,666 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because some of the claims of the patent "anticipate" some of the claims of the application and some of the application claims would have been obvious over the patent claims. Both inventions require a housing, tissue engaging members [tissue everting members; note that the everting members inherently have a deployment member in order to perform the recited deploying function], jaw members that move between open and closed positions, an elongated shaft having recesses [camming surface], and a conductive attachment member [electrode; note: in which the inwardly extending attachment as recited in the application claims forms a cooperating "camming

surface" as recited in the patent claims]. Accordingly, the application claims are not patentably distinct from the patent claims. Here, the more specific patent claims (i.e., specifically requiring the attachment be an "electrode" for closing the opening) encompass the broader application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

With further respect to claim 20, it is well known in the art to use spring members with actuators, for example, clip appliers, in order to bias the jaws of the device into either an open position or a closed position. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the '666 invention with a spring member to bias the jaw members closed. Doing so would yield a simplified device requiring only a single input from the user to the actuator to open and close (or operate) the jaws.

With further respect to claims 29 and 35, providing medical devices with lumens or slots for tracking over a guidewire is well known in order to minimize damage to healthy tissue while inserting the device and tracking the device to the proper position within the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the elongated shaft of the '666 invention with a guidewire lumen or slot in order to be able to track the device over a

properly positioned guidewire within the body, thus facilitating proper placement within the body while reducing the risk of damaging healthy tissue.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggests the limitations as set forth in claim 18 in combination with the additional limitations set forth in claim 29; more specifically, the requirement of recesses in the elongated shaft adjacent its distal end, the inwardly depending tissue contacting portions of the jaw members being configured and dimensioned for receipt by the recesses (as depicted in Figure 7A). The applicant discloses the combined limitations provide the advantage of effectively everting and fusing tissue with a device having a reduced profile.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose e-mail is Melanie.tyson@uspto.gov and telephone number is (571)272-9062. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Primary Examiner, Art Unit 3773
April 14, 2011